

Structured Product Labeling (SPL) OTC Sub-team Teleconference

November 2, 2009, 1:00 – 2:00 pm ET

Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

- ✚ Cheryl Blik, Teva Pharmaceuticals, Inc.
- ✚ David Brown, Colgate Palmolive Company
- ✚ Terry Brunone, GlaxoSmithKline
- ✚ Gail Burke, Procter & Gamble
- ✚ Shelia Dy Juanco, Medline Industries, Inc.
- ✚ Maureen Kapustynski, Cadbury
- ✚ Mike Koenig, FDA
- ✚ Juris Lazdins, Novartis Consumer Health, Inc.
- ✚ Carolyn Lindsay, Cardinal Health
- ✚ Paula Markert, GlaxoSmithKline (sub-team co-leader)
- ✚ Kathryn Moreng, Bayer Consumer HealthCare
- ✚ Devon Morgan, Perrigo Company (sub-team co-leader)
- ✚ Priscilla Mott, Johnson& Johnson Consumer & Personal Products Worldwide
- ✚ Alison Rago, Intagras
- ✚ Janet Riffitts, McNeil Consumer Healthcare
- ✚ Eva Rivera, Glemser Technologies Corporation
- ✚ Howard Shatz, Data Conversion Laboratory, Inc.
- ✚ Siobhan Stevens-Miles, Merck & Co., Inc.
- ✚ Carl Strotz, Pfizer Consumer Healthcare (formerly Wyeth Consumer Healthcare)
- ✚ Beth Thompson, Medline Industries, Inc.
- ✚ Cynthia Thompson, Kimberly-Clark Corporation
- ✚ Craig Trautman, Intagras
- ✚ Karen Vescovi, Church & Dwight Co., Inc.
- ✚ Ann Vu, FDA
- ✚ Elise Wolf, Combe Incorporated
- ✚ Barbara Wolfe, Pfizer Consumer Healthcare (formerly Wyeth Consumer Healthcare)
- ✚ Marcia Howard, CHPA staff (sub-team liaison)

II. Next Standing Teleconference: November 16, 2009, 1:00pm ET

III. FDA Data Council Information (*Not All-inclusive*)

- A. SPL Terminology Update – UNIIIs (Updated November 3, 2009) *added since teleconference concluded*
 - 1. UNII update -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml62523.htm>
 - 2. Updated terminology XML Files (include updated UNII XML file) -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml69455.htm>
- B. SPL Terminology Update – UNIIIs (Updated October 31, 2009)
 - 1. UNII update -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml62523.htm>
 - 2. Updated terminology XML Files (include updated UNII XML file) -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml69455.htm>
- C. SPL Terminology Update – UNIIIs (Updated October 27, 2009)
 - 1. UNII update -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml62523.htm>
 - 2. Updated terminology XML Files (include updated UNII XML file) -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml69455.htm>
- D. SPL Terminology Update – UNIIIs (Updated October 15, 2009)
 - 1. UNII update -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml62523.htm>
 - 2. Updated terminology XML Files (include updated UNII XML file) -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml69455.htm>

IV. Upcoming SPL Educational Forums/Information (*For Your Information*)

FDA SPL R4 Training Sessions – Please visit website for updated information regarding training courses.

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml55705.htm>

- A. **FDA Training Sessions:** Monday webinars at 10:00 am ET and Q&A sessions at 11:30 am ET (same for both; cancelled for Federal holidays)
Telephone number: 1-866-775-9435
Participant pass code: 5753366
Please dial-in early as there are a limited number of ports and when they are exhausted, no one else will be able to connect to the conferences.

FDA will be closed on Wednesday, November 11, 2009, in recognition of the Federal holiday (Veteran's Day).

FDA has released a series of e-Training Books that are available on the SPL Wiki page as another SPL resource to industry.
(<http://spl-work-group.wikispaces.com/>)

- B. **SPL Process Communication Forum (Process Team):** Alternating Wednesdays 1:00 - 2:30 pm ET (unless cancelled; opposite to ERDL calls)
Telephone number: 877-423-2663
PIN#: 558089
Please email Process Team co-leaders Terry Brunone (Theresa.M.Brunone@gsk.com) or Mary Beth Wilusz (mary_beth_wilusz@merck.com) if you want to get the email information.
- C. **SPL ERDL Sub-team calls:** Alternating Wednesdays at 1:00 pm ET (unless cancelled)
Telephone number: 866-217-3840
Conference Code: 4286445422
Please email sub-team leader Michael Fahmy if you want to get the email information (michael.fahmy@bms.com).
- D. **SPL Generics Sub-team calls:** First Tuesdays of each month at 1:00 pm ET (unless cancelled)
Telephone number: 866-618-6746 (toll-free)
201-527-2133 (international/caller paid)
Access Code: 8957842
Please email sub-team leader Virginia Hogan if you want to get the email information (Virginia.Hogan@tevausa.com).

- E. Others – *Note: although members of the various SPL sub-teams may be involved in the following programs, no endorsement or recommendation is implied*
1. CBI's Forum on [FDA's Structured Product Labeling \(SPL R4\)](#), December 8-9, 2009, in Washington, DC
 2. DIA Webinar: [Preparation of Electronic Drug Establishment Registration and Drug Product Listing \(eDRL\) Submissions in SPL format: What You Need to Know](#). (December 8, 2009)

V. Discussion Topics

- A. SPL Content of Labeling Draft Guidance
<http://edocket.access.gpo.gov/2009/pdf/E9-25940.pdf> (Notice)
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf> (Draft Guidance)

The revised draft guidance was released on October 28, 2009. Sub-team members were asked to review the document to determine if collective comments should be provided to the agency. Some of the key revisions to the document are listed below.

- Question 3, 9, 10, 23, 28, and 31 (please see draft guidance)

Other questions in the draft guidance technical Q&A might be important to your organization so it is recommended that companies read the entire document.

- B. Submission on Posting OTC information to DailyMed/FDA Facts page
Marcia Howard (CHPA staff) explained that at this time it is probably not beneficial to send input to FDA on posting of OTC information to the NLM DailyMed/FDA Facts page at this time. The reasons for this decision include (in random order):

- few reasons were given why OTC monograph drugs should *not* be listed which was one of the key reasons FDA was seeking industry input
- the length of time that has transpired since the initial request for input (as time was permitted for internal discussion, collection of responses, and drafting of the submission)
- the fairly small number of responses compared to the number of sub-team members and,
- lack of complete agreement on the issue by respondents.

Unless sub-team members object, the draft submission will be tabled for now and revisited for future submission if necessary. Sub-team members can contact Marcia privately to discuss the matter if desired. During the call, no objections were voiced.

C. Import Issues

Sub-team members were asked to contact Marcia if there are specific examples of import issues related to electronic drug listing. FDA is conducting training as quickly as possible but there is still some import staff that may not be aware of SPL. Lonnie Smith, of the FDA, has graciously offered to assist with import issues as much as possible but a request will be made to speak to FDA management about the problems. Note that Lonnie/FDA can only help if the listing process has been completed satisfactorily; they cannot provide assistance if the SPL submission has not been properly done. Terry Brunone, of GlaxoSmithKline and SPL Process Team co-leader, mentioned that members should advise Lonnie about the particular district that may be unaware of SPL to help target training activities.

FDA has suggested the following steps to help minimize the chance of delayed importation of products.

Tips provided by Terry Brunone and available on the SPL Wiki page:

Here a few tips. With respect to import issues, if you send an email to the SPL account (SPL@fda.hhs.gov), please indicate in the subject header (in no specific order):

1. If this is an urgent issue – please mark urgent only when it really is...if you anticipate an import issue, please send FDA a message as early as possible so they will have adequate time to research the issue and reply to your message
2. That it is related to an import issue
3. The specific product/s for which you are requesting assistance

In the body of the message, provide any additional details that will help FDA research the issue as quickly as possible. If there are problems at the border, include the name and number of the Port of Entry in communications and/or district office to the SPL@fda.hhs.gov

FDA is doing all it can to get the import staff trained but until this occurs (and there are a lot of people that must be made aware of the changes so it won't happen immediately), they recognize that companies may need their assistance to resolve some of the import questions that arise. Hopefully these tips will help.

from: <http://spl-work-group.wikispaces.com/Import+Q-and-A> and
<http://spl-work-group.wikispaces.com/Questions+from+August+29+Process+Call>

VI. Updates

- A. Requesting UNII for Simethicone – see questions below
One company has submitted information regarding simethicone. Interested sub-team members should consult with their internal colleagues and send their responses to Marcia Howard by November 16, 2009.
- B. Use of X-forms
JoAnn Witek, regulatory consultant, kindly submitted a possible solution to issues related to use of the X-forms and jpg files. FDA also recently released a Training eBook on X-forms that might be helpful (available at the Wiki site and circulated via email).

VII. Other

- A. The agenda will now be ordered so the topics that are for information only will be covered first to allow those who might arrive a few minutes late to be present for the discussion items.
- B. Changes to the validation rules that have been recently circulated by the agency ***do not*** reflect any changes in regulations, rules, or requirements. They are meant to prevent information from entering the system and later requiring additional corrective action to be taken. As it is unlikely that companies will get prior warning about changes to the validation rules, please be as careful and as accurate as possible when completing your electronic submission to minimize the change of failing validation.

MDH/11-02-09

SPL OTC Sub-team 2 November 2009 110209.doc
Last Revised: November 5, 2009 Sent: November 5, 2009

Message received from SPL OTC sub-team member from FDA (identifying information removed):

Requesting UNII for Simethicone

You requested for one UNII to be assigned to simethicone instead of the two substances. It is the FDA Substance Registration System team's position that simethicone can always be listed as a mixture of a given type dimethicone and silicon dioxide.

Due to the amount of recent requests for assignment of a UNII for simethicone by several companies, before we can even consider the assignment a UNII to this term we have some questions.

Note that these are not to be considered as regulatory questions and are only posed as questions due to your request for the assignment of a term to be utilized in the product data elements section of a listing SPL document. You are not obligated in any way to answer these questions and should you opt to reply, your responses will not have any bearing on the approval (if applicable) or listing of your drug.

1. From some of the formulation sheets we have received with requests for an assignment of a UNII for simethicone, it appears that the potency listing is actually based on the amount of dimethicone. Do all the manufactures use a USP grade of simethicone where the amount of silicon dioxide is limited to between 4 and 7%? For example when you list 125 mg/tablet does this mean there will always be between 4 and 9 mg of silicon dioxide and 125 mg of dimethicone or does it mean 125 mg of the mixture dimethicone + silicon dioxide? If there is more than 7% silicon dioxide in a table do you list silicon dioxide as a separate ingredient?
2. What type of dimethicone is typically used? There are a variety of types of Dimethicone each of which differ by molecular weight and would get a separate UNII.
3. Which dimethicones are typically used in the manufacturing of simethicone for pharmaceutical grade material? Is this something that is always controlled? The literature indicates that dimethicones between 20 and 3000 CS are typically used. Unfortunately the USP monograph does the specify the need for the label to indicate the type of dimethicone used.
4. Do manufacturers always use the same type of dimethicone in a given product? The type of dimethicone may influence the performance of the product.